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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,424	06/28/2002	Muhammed Majeed	108064-00049	2480

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,424	MAJEED ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *148-151,175 and 177-191* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *148-151, 175 and 177-191* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In view of the appeal brief filed on August 16, 2004, PROSECUTION IS HEREBY REOPENED. A new ground of rejection set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Currently, claims 148-151, 175 and 177-191 are pending in this application.

Claims 148-151, 175 and 177-191 are examined on the merits herein.

Applicant's arguments in the appeal brief filed on August 16, 2004 with respect to the rejection of claims 148-151 and 175 and 177-191 made under 35 U.S.C. 112, first paragraph, as containing new subject matter have been fully considered and found persuasive to remove the rejection since the specification at page 17-22 is seen to support the limitations in the claims. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 148-151, 175 and 177-191 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling the instant particular combination for treating a specific and particular autoimmune disease, does not reasonably provide enablement for treating any autoimmune diseases, encompassed by the claims by administering the boswellic acids compositions.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without ***undue experimentation***. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a method of treating any autoimmune diseases including those recited in claim 151 herein.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since these claims reads on treating any autoimmune diseases including those recited in claim 151 herein.

Regarding the *Wands* factor (4) the predictability or unpredictability of the art:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the recitation encompasses any autoimmune diseases, which are known to be involved various, many possible, different, separate and independent, even unknown pathology, etiologies, or symptoms. The method for the treatment of an autoimmune disease is not one but at least two distinct, separate, and independent methods. For example, as defined by Ninham et at. (WO 85/05031, PTO-892), the immune response in a human or animal subject can be suppression or enhancement (see page 1-2). Autoimmune diseases can be treated by artificial suppression (immunosuppression) or enhancement (immunopotentation), wherein these two treatments are involved in distinct and separate agents, processes and mechanisms, and most importantly which are in both opposite directions.

The skilled artisan would view that, treating any autoimmune diseases, encompassing both suppression (immunosuppression) and enhancement (immunopotentation), by administering the VERY same ~~the~~ boswellic acids composition, is **highly *unpredictable***. Therefore, the skilled artisan would view that the treatment of

all autoimmune diseases herein, including 17 diseases listed in claim 151 herein by administering the same composition herein, is highly *unpredictable*.

In regard to these *Wands* factors, (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary:

In the instant case, **no** working examples are presented in the specification as filed showing how to treat a single autoimmune disease, i.e., no testing results provided.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the broad treatment of any autoimmune diseases encompassed by the instant claims. As a result, necessitating one of skill to perform an exhaustive search and undue experimentation for the embodiments of treating any autoimmune diseases recited in the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in *undue experimentation*, with no assurance of success.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 148-151, 175 and 177-191 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Koji et al. (JP 0428809, see the English translation).

Koji et al. in JP 0428809 discloses that specific boswellic acids such as β–boswellic acid, acetyl-β–boswellic acid, 11-keto-β–boswellic acid, and acetyl-11-keto-β–boswellic acid (see formula I of the structures at page 2 of the English translation) are useful in pharmaceutical compositions and in the method for treatment of autoimmune diseases including systemic erythematosis and articular rheumatism in humans since β–boswellic acids exhibit a good and complemental activity-inhibiting particular autoimmune diseases such as chronic rheumatoid arthritis and psoriasis (see page 3-4). Moreover, Koji et al. also discloses the methods or processes how obtain and separate each instant boswellic acid from boswellic acids mixture in the plants. Furhter, the structural formula disclosed in JP 0428809 clearly encompasses all four instant boswellic acids. JP 0428809 discloses the composition comprising β–boswellic acid, acetyl-β–boswellic acid, 11-keto-β–boswellic acid, or acetyl-11-keto-β–boswellic acid acetyl-11-keto-β–boswellic acid in their effective amounts. See Example 1-6, and the testing data of the Examples therein as working examples.

JP 0428809 does not expressly disclose the instant particular percentage or range of each of four boswellic acids employed in pharmaceutical compositions for methods for treatment of particular autoimmune diseases.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine particular percentage or range of each of four boswellic acids employed in pharmaceutical compositions for methods for treatment of particular autoimmune diseases wherein at least 5% w/w of β–boswellic acid, at least 5% w/w of acetyl-β–boswellic acid, at least 15% w/w of 11-keto-β–boswellic acid and at least 14% w/w of acetyl-11-keto-β–boswellic acid or other instant particular amounts of boswellic acids.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine particular percentage or range of each of four boswellic acids employed in pharmaceutical compositions for methods for treatment of particular autoimmune diseases wherein at least 5% w/w of β–boswellic acid, at least 5% w/w of acetyl-β–boswellic acid, at least 15% w/w of 11-keto-β–boswellic acid and at least 14% w/w of acetyl-11-keto-β–boswellic acid or other instant particular amounts of boswellic acids, since the testing results and working examples of the instant boswellic acids useful for treating particular autoimmune diseases are known according to JP 0428809.

Therefore, the determination and optimization of effective amounts of known active agents to be administered based on the known parameters, testing results and working examples provided by JP 0428809, are considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Claims 148-151, 175 and 177-191 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Taneja et al. (EP 0755940, of rechord).

Taneja et al. discloses that boswellic acids herein such as β–boswellic acid, acetyl-β–boswellic acid, 11-keto-β–boswellic acid, and acetyl-11-keto-β–boswellic acid (Formula I-IV therein at page 3) are useful in pharmaceutical compositions and in the method for treatment of inflammatory diseases including arthritis in humans since these boswellic acids exhibit anti-inflammatory action. See page 2 lines 49-50. Taneja et al. also discloses that the pharmaceutical composition therein comprising these β–boswellic acids in specifically effective amounts, e.g., 35-55% w/w of β–boswellic acid(which reads on at least 5% w/w), 25-45% w/w of acetyl-β–boswellic acid (which reads on at least 5% w/w), 4-14% w/w of 11-keto-β–boswellic acid, and 3-13% w/w of acetyl-11-keto-β–boswellic acid (see page 5 lines 15-26).

Taneja et al. does not expressly disclose the effective amounts of 11-keto-β–boswellic acid and acetyl-11-keto-β–boswellic acid employed in pharmaceutical compositions for methods for treatment of autoimmune diseases in which at least 15% w/w of 11-keto-β–boswellic acid and at least 14% w/w of acetyl-11-keto-β–boswellic acid.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine the effective amounts of 11-keto-β–boswellic acid and acetyl-11-keto-β–boswellic acid employed in pharmaceutical compositions for methods for treatment of autoimmune diseases in which at least 15% w/w of 11-keto-β–boswellic acid and at least 14% w/w of acetyl-11-keto-β–boswellic acid.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of 11-keto-β–boswellic acid and acetyl-11-keto-β–boswellic acid employed in pharmaceutical compositions for methods for treatment of autoimmune diseases in which at least 15% w/w of 11-keto-β–boswellic acid and at least 14% w/w of acetyl-11-keto-β–boswellic acid, since the determination and optimization of effective amounts of known active agents to be administered based on the known effective amounts according to Taneja et al, are considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Moreover, one of ordinary skill in the art would recognize that autoimmune diseases broadly encompass inflammatory diseases. Hence, the teachings of Taneja et al. have clearly provided the motivation for the instant invention.

Thus the claimed invention as a whole is seen prima facie obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner, AU 1617
November 15, 2004

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER